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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,488

04/06/2005

Enok Tjotta

5051-639

5328

466 7590 09/17/2008

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EXAMINER

REDDIG, PETER J

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

09/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,488	Applicant(s) TJOTTA, ENOK	
	Examiner PETER J. REDDIG	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-61 is/are pending in the application.
- 4a) Of the above claim(s) 42,43,45 and 47-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-41,44,46 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Election filed June 9, 2008 in response to the Office Action of May 8, 2008 is acknowledged and has been entered.

Applicant's election with traverse of Group I, claims 28-46 and 61 and the species drugs is acknowledged.

Applicant argues that traverse is proper because the subject matter of Groups 1, 2 and 3 are so intimately interrelated that no undue burden of search and/or consideration is placed upon the Examiner.

Applicant's argument has been considered, but has not been found persuasive because burden of search is not the criteria for proper restriction under PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

Applicant argues that further, unity in the invention was found in the International Preliminary Examination Report the International Search Report in the PCT application.

Applicant's argument has been considered, but has not been found persuasive because the finding of unity in the International Preliminary Examination Report the International Search Report is not binding on the national stage application.

Applicant argues that, additionally, in the Official Action, prior art is relied upon to assert that the invention listed as Groups 1-3, failed to relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features.

Applicant argues that, however, this art (VERMA et al. and WO 01/00585) are evidence that consideration and/or search has already been performed on the present invention. There is

Art Unit: 1642

therefore no additional burden placed upon the Examiner to continue consideration and examination on the merits of all of the claims of the present invention.

Applicant's argument has been considered, but has not been found persuasive because burden of search is not the criteria for proper restriction under PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

However, in view of the prior art, the agents toxin/potential toxins and component of a physiological or a pathological process, will be rejoined for examination.

For the reasons set for above, the restriction requirement is deemed to be proper and is therefore made FINAL.

2. Claims 28-61 are pending.
3. Claims 42, 43, 45 and 47-60 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.
4. Claims 28-41, 44, 46, and 61 are currently under consideration.

New Grounds of Objection/Rejection

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because multiple drawing are referred to by the same figure number. It is noted that the different views must be numbered in consecutive Arabic numerals, starting with 1, independent of the numbering of the sheets and, if possible, in the order in which they appear on the drawing sheet(s), see CFR 1.84 (u)(1).

Art Unit: 1642

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Experiment 18, Fig. 2.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 28-41, 44, 46, and 61 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-4, 44 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps for conducting an in vitro clonal test, the steps for testing the effect that different degrees of local collocation of cells has on the effect of

Art Unit: 1642

said agent, the steps for an in vivo metastasizing test, and the steps for an in vivo test of clonal growth of immune cells.

Claim 28 recites the limitation "immunization of the subject " in step d. However there is no prior reference to the subject, thus there is insufficient antecedent basis for this limitation in the claim.

Claim 29 recites the limitation "said cloning test" in claim 28. There is insufficient antecedent basis for this limitation in the claim. Amendment of the claim "said in vitro clonal test in step a) of claim 28" would obviate this instant point of rejection.

Additionally, the terms "liberation of cells" and "potential toxin" also renders claims 36, 37, 40, and 61 indefinite as they are also not defined by the claim, the specification does not teach what the terms "liberation of cells" and "potential toxin" encompass.

Section 2171 of the M.P.E.P. states

There are two separate requirements set forth in this paragraph:

- (A) the claims must set forth the subject matter that applicants regard as their invention; and*
- (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.*

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite — i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

In the instant case, one of skill in the art could find representative examples in the art which have been defined in such terms, however, it is unclear at what point one of skill in the art

Art Unit: 1642

would be infringing on the claims without limitations as to the metes and bounds of what is encompassed by the term terms “liberation of cells” and “potential toxin” .

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 28-41, 44, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The method for testing and selecting an agent to determine whether said agent inhibits or stimulates clonal growth, comprising the steps: a) testing said agent with an in vitro clonal test to study the effect of said agent on cloning; b) testing the effect that different degrees of local collocation of cells has on the effect of said agent on cloning; c) testing said agent with an in vivo metastasizing test that determines the effect of said agent on metastasizing cells; d) testing said agent with an in vivo test of clonal growth of immune cells stimulated by immunization of the subject; e) evaluating the results obtained with steps a), b), c) and d) ; and f) determining and selecting said agent claimed in Claims 28-41, 44, and 46 has no clear support in the specification and the claims as originally filed.

In the remarks filed January 11, 2008. Applicant pointed to support in the specification at pages 26, lines 19-27, and Examples 10-12. A review of the specification discloses support for: A clonal test to study the effect on cloning of said substances and; a collocation inhibition

Art Unit: 1642

test to study how increase of local cell concentration (increase of cell collocation) may decrease or abrogate the effect of said substances or physical effects on the process of cloning and on toxicity and; tests for the ability of said substances or physical effects to influence the development of metastases in other ways than on cloning, e.g. on export of metastatic cells from a malignant tumour or location containing tumour cells. The present invention comprises further the use of the compounds found by said method for preparing pharmaceutical preparations or procedures for the treatment or prophylactics of cancer, arteriosclerosis, auto-immunity, rejection of transplants and the outcome of exposure to radioactivity or other physical effects. Also the use of 4-OH-OPB for preparing a pharmaceutical preparation for the treatment or prophylactics of said diseases or effects is part of the present invention (pages 26, lines 19-27); testing the effect of 4-OH-OPB on number of cells in spleen with production of antibodies against sheep red cells after immunization (Example 10); testing Herpes Virus Type 1 (HSV1) for sensitivity against 4-OH-OPB (Example 11); and testing Herpes Virus Type 2 for sensitivity against 4-OH-OPB (Example 12).

The suggested support is not found persuasive because there is nothing in the specification to suggest the method comprising the combination of steps in claim 28 nor is there support for step d): testing said agent with an in vivo test of clonal growth of immune cells stimulated by immunization of the subject. The subject matter claimed in claims 28-41, 44, and 46 broadens the scope of the invention as originally disclosed in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1642

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 28-32, 34-36, 38-41, 44, 46 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Prechel et al. (Cancer Letters, 1995, 92: 235:242) as evidenced by Car et al. (Toxicologic Pathology, 1999, Vol. 24:58-63).

The claims are drawn to:

28. (new) A method for testing and selecting an agent to determine whether said agent inhibits or stimulates clonal growth, comprising the steps:

a) testing said agent with an in vitro clonal test to study the effect of said agent on cloning; b) testing the effect that different degrees of local collocation of cells has on the effect of said agent on cloning; c) testing said agent with an in vivo metastasizing test that determines the effect of said agent on metastasizing cells; d) testing said agent with an in vivo test of clonal growth of immune cells stimulated by immunization of the subject; e) evaluating the results obtained with steps a), b), c) and d) ; and f) determining and selecting said agent.

29. (new) The method according to claim 28, wherein said cloning test comprises

i) seeding of cells in a suitable medium with or without growth factor,
ii) incubating said cells in suitable temperature and atmosphere with said agent; and
iii) determining the effect of said agent on cloning of said cells.

30. (new) The method according to claim 29, wherein

the clonal test is performed in: i) a fluid medium; or ii) a semisolid or solid medium

Art Unit: 1642

31. (new) The method according to claim 29, wherein the cells are malignant cells, normal cells, cell lines, transformed cells and cells from a tumor or malignant disease of a patient.

32. (new) The method according to claim 29, wherein the cells are immune cells that are cloned and selected after immunization.

34. (new) The method according to claim 29, wherein the medium further comprises insulin, serum, insulin like growth factors, cytokines, or serum extenders, and conditioned medium or a combination of these.

35. (new) The method according to claim 28, wherein step b) comprises:
i) transplanting a tumor cell to an animal, or seeding experimental cell cultures with any of the mentioned cells; ii) treating the animal with said tumor cell or the cells in experimental cell cultures with said agent; iii) determining the effect of said agent on cloning of said tumor cell in the animal or of the cells in experimental cell cultures.

36. (new) The method according to claim 28, wherein step c) comprises:
i) injecting tumor cells in an animal to develop metastases, ascites or local tumors; ii) applying the agent; and iii) determining the effect of said agent to affect the liberation of cells, migration, and the ability to form a local tumor

38. (new) The method according to claim 28, wherein said method detects an agent that causes an increased number of clones and/or facilitates the growth and migration of metastases and/or growth of primary tumors.

Art Unit: 1642

39. (new) The method according to claim 28, wherein the agent is selected from the group consisting of drugs, food, food additives, toxins microbes, and a component of a physiological or a pathological process.

40. (new) The method according to claim 28, wherein the agent is selected from the group consisting of drugs, food, food additives, toxins, potential toxins, microbes, a component of a physiological or a pathological process.

41. (new) The method according to claim 28, wherein the agent is a drug

44. (new) The method according to claim 28, wherein the agent is a toxin.

46. (new) The method according to claim 28, wherein the agent is a component of a physiological or a pathological process.

61. (new) A method for testing an agent to determine whether said agent inhibits or stimulates clonal growth, comprising the steps:

a) testing said agent with an in vitro clonal test for studying the effect of said agent on cloning, said cloning test comprising: i) seeding of cells in a medium with or without growth factor, ii) incubating said cells in a suitable temperature and atmosphere with said agent; and iii) determining the effect of said agent on cloning of said cells; b) testing the effect that different degrees of local collocation of cells have on the effect of said agent on cloning, said testing comprising: i) transplanting a tumor cell to an animal, or seeding experimental cell cultures with BHK21/c13 or BHK21/CI3 cells transformed with polyoma virus; ii) treating said tumor cell in the animal or the cells in experimental cell cultures with said agent; iii) determining the effect of said agent on cloning of said tumor cell or stimulated immune cells in the individual or the cells in experimental cell cultures; c) testing said agent with an in vivo metastasizing test to determine

Art Unit: 1642

the effect of said agent on metastasizing cells, said step comprising: i) injecting tumor cells in an animal to develop metastases, ascites or local tumors; ii) applying the agent; and iii) determining the effect of said agent to affect the liberation of cells, migration, and the ability to form local tumor; d) evaluating the results obtained with steps a), b), and c); and e) determining whether said agent inhibits or stimulates clonal growth.

Prechel et al. teach testing the effect *in vivo* effect of IL-12 on colony formation of myeloid cells in mice that had been immunized with Lewis lung carcinoma LLC-LN7 tumor cells with IL-12, which stimulates the growth of myeloid colonies, see p. 237-2nd col. figure 1, and Table 1. Prechel et al. teach testing the effect of IL-12 on colony formation of myeloid cells *in vitro* by seeding bone marrow and spleen cells in 1 ml of semisolid RPMI-1640 medium supplemented with 20% FBS and 0.3% agar,, see p.236, p. 237-2nd col. and Fig. 2. This colony forming assay would clone and select cells for cells that grow in the presence of IL-12 that are from mice immunized with LLC-LN7 tumor cells. Prechel et al. teach injecting mice with tumor cell, treating with IL-12 and determining the effect of palpable local tumor size and the formation of metastatic lung nodules, see p. 240 and Fig. 6.

It is noted that, given the indefinite nature of the term "liberation of cells", it is assumed for examination purposes that "liberation of cells" is the formation of tumor metastasis.

Car et al. teach that IL-12 is a heterodimeric cytokine produced by several types of cells that is used as a drug, but also has toxic effects, see p. 58. Thus, IL-12, is drug, toxin, and a component of a physiological process.

Although the reference does not specifically state that they determined the effect of IL-12 on migration, given that is well known in the art that metastases involves the migration of cells

Art Unit: 1642

from one location in the body to another location in the body, the claimed method appears to be the same as the prior art method, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the method of the prior art does not possess the same material, structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prechel et al. (Cancer Letters, 1995, 92: 235:242), in view of De Asua et al. (Proc. Natl. Acad. Sci USA, 1973, 70:1388-13920) and in view of Kamei H. (Cell Biol. Int. Rep. Jan. 1987, 11 (1): 35-41).

Art Unit: 1642

Claim 33 is drawn to the method according to claim 29, wherein the cells are selected from the group consisting of BHK21/c13, and BHK21/C13 cells transformed with polyoma virus.

Prechel et al. teach as set for above, but do not teach using BHK21/c13, and BHK21/C13 cells transformed with polyoma virus .

De Asua et al. teach testing the effect of insulin and cAMP on BHK21/13 agar colony formation, see Abstract and Table 1.

Kamei H. teaches that the BHK21/13 cells of De Asua cells are BHK21/c13 cells, see Introduction p. 35. Kamei et al. also teaches using a BHK21/c13 clone to study the effects of retinoic acid on anchorage independent growth of the BHK21/c13 clone cells, see Abstract..

It would have been *prima facie* obvious at the time the invention was made to use the BHK21/c13 cell agar colon assay of De Asua in combination with the method of Prechel et al. to determine the effect of IL-12 on BHK21/c13 cell anchorage independent growth. One of skill in the art would have been motivated to use BHK21/c13 cell cells to determine the breadth of IL-12 activity on different cell types. As the skill in the art is high, one of skill in the art would have had a reasonable expectation of success of using BHK21/c13 cells as they were a well known model for assaying the effects of agents *in vitro* cell studies of clonal cell growth.

10. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prechel et al. (Cancer Letters, 1995, 92: 235:242) in view of US Pat. No. 4,744, 985 (Tami et al., May 17, 1988).

Claim 37 is drawn to the method according to claim 36, wherein said tumor cells are transplanted Ehrlich carcinoma cells.

Prechel et al. teach as set for above, but do not teach tumor cells are transplanted Ehrlich carcinoma cells.

US Pat. No. 4,744, 985 teaches using Ehrlich tumor cells transplanted intraperitoneally or into the armpits of mice to determine the antitumor activity of bacterial extracts, see cols.20-24.

It would have been *prima facie* obvious at the time the invention was made to use the Ehrlich tumor cells of US Pat. No. 4,744, 985 in the examination of tumor growth/metastasis method of Prechel et al. to determine the effect of IL-12 on transplanted Ehrlich tumor cell growth and metastasis. One of skill in the art would have been motivated to use Ehrlich tumor cells to determine the breadth of IL-12 activity on different tumor types. As the skill in the art is high, one of skill in the art would have had a reasonable expectation of success of using Ehrlich tumor cells as they were a well known model of tumor formation.

11. All other objections and rejections recited in the Office Action of September 11, 2007 are withdrawn.

12. No claims allowed.

13. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

Art Unit: 1642

A reply under 37 CFR 1.113 to a final rejection must include the appeal form, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

14. Applicant's amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R., 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R., 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

Art Unit: 1642

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/

Examiner, Art Unit 1642

/Karen A Canella/

Primary Examiner, Art Unit 1643

/PJR/